

Structured Product Labeling (SPL) OTC Sub-team Teleconference

October 5, 2009, 1:00 – 2:00 pm ET

Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

- + Joan Berger, Image Solutions, Inc.
- + Cheryl Blik, Teva Pharmaceuticals, Inc.
- + David Brown, Colgate Palmolive Company
- + Pete Carlson, EcoLab
- + Shelia Dy Juanco, Medline Industries, Inc.
- + Mary Beth Fritz, Prestige Brands Holdings, Inc.
- + Chris Guay, Procter & Gamble
- + Maureen Kapustynski, Cadbury
- + Mike Koenig, FDA
- + Juris Lazdins, Novartis Consumer Health, Inc.
- + Paula Markert, GlaxoSmithKline (sub-team co-leader)
- + Priscilla Mott, Johnson& Johnson Consumer & Personal Products Worldwide
- + Alison Rago, Intagras
- + Janet Riffitts, McNeil Consumer Healthcare
- + Eva Rivera, Glemser Technologies Corporation
- + Gary Saner, Reed Technology & Information Services, Inc.
- + Howard Shatz, Data Conversion Laboratory, Inc.
- + Beth Thompson, Medline Industries, Inc.
- + Karen Vescovi, Church & Dwight Co., Inc.
- + Ann Vu, FDA
- + Lynn Walks, i4i
- + JoAnn Witek, Consultant
- + Elise Wolf, Combe Incorporated
- + Barbara Wolfe, Wyeth Consumer Healthcare
- + Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: October 19, 2009, 1:00pm ET

III. FDA Data Council Information (*Not All-inclusive*)

Listing of OTC Active Ingredients: [By Alphabetical Listing](#) and [By Monograph/Category](#)
(updated September 28, 2009)

IV. Upcoming SPL Educational Forums/Information (*For Your Information*)

FDA SPL R4 Training Sessions – Please visit website for updated information regarding training courses.

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>

A. **FDA Training Sessions:** Monday webinars at 10:00 am ET and Q&A sessions at 11:30 am ET (same for both; cancelled for Federal holidays)
Telephone number: 1-866-775-9435
Participant pass code: 5753366
Please dial-in early as there are a limited number of ports and when they are exhausted, no one else will be able to connect to the conferences.

Training sessions and Q&A session are cancelled for Monday, October 12, 2009, due to the Federal holiday.

FDA has released a series of e-Training Books that are available on the SPL Wiki page as another SPL resource to industry:
(<http://spl-work-group.wikispaces.com/SPL+eBooks+-+Graphic+Guides>).

Because FDA believes finalizing other eBooks is key to maximizing outreach to constituents, this will be a top agency priority at this time. Once the eBooks have been published, additional webcast training, including category-specific courses, will be scheduled.

B. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)
Telephone number: 877-423-2663
PIN#: 558089
Please email Process Team co-leaders Terry Brunone (Theresa.M.Brunone@gsk.com) or Mary Beth Wilusz (mary_beth_wilusz@merck.com) if you want to get the email information.

C. **SPL ERDL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)
Telephone number: 866-217-3840
Conference Code: 4286445422
Please email sub-team leader Michael Fahmy if you want to get the email information (michael.fahmy@bms.com).

D. **SPL Generics Sub-team calls:** First Tuesdays of each month at 1:00 pm ET (unless cancelled)
Telephone number: 866-618-6746 (toll-free)
201-527-2133 (international/caller paid)
Access Code: 8957842
Please email sub-team leader Virginia Hogan if you want to get the email information (Virginia.Hogan@tevausa.com).

V. Discussion Topics

A. Import Issues

Some companies have experienced difficulties with imported products being delayed due to the lack of paper verification for drug listing. The agency continues its educational outreach to import staff but recognizes that not all staff may be aware of the new e-Listing process. FDA has suggested the following steps to help minimize the chance of delayed importation of products.

1. For **urgent** import issues (e.g., product is being held at port)
 - a. In subject line, include “urgent import issue and product name.” Please use “urgent” only if it is truly an urgent matter.
 - b. In body of message, include Core ID, product name, port of entry (very important), and any other pertinent information (e.g., contact info if different from SPL info).
 - c. Send message to SPL@fda.hhs.gov (please do not send copy to Lonnie Smith directly as he will then receive two copies).
2. For **proactive** assistance with import issues (e.g., a monograph OTC product that cannot be viewed online at DailyMed and is not sitting at the border but will be arriving soon), include the same info as for urgent issues except in the subject line use “import issue and product name” without “urgent.”

B. Requesting UNII for Simethicone

A request was made for assignment of a UNII for simethicone. Simethicone is listed as in the USP as an active ingredient but the Substance Registration Team (SRT) has asked for a breakdown of the components. In order to consider the request for a UNII, FDA has requested additional information from companies using this ingredient (see FDA questions below in blue). **Companies that are willing to do so should provide responses to the questions posed by the agency (provided at the end of this document) to Marcia Howard (CHPA staff) no later than November 16, 2009.** There were six companies represented on the SPL OTC sub-team that are known to be affected by this issue.

It is unclear why it appears there may be a deviation from the USP listing for assigning a UNII to simethicone. According to Joan Berger (Image Solutions) simethicone is used as an inactive in prescription drugs (which are required to

list inactive ingredients but not quantity) so it may be helpful to explore what has been used on the Rx side. There is a question about whether this request could have broader implications for other active ingredients with similar issues because getting product details on proprietary ingredients from third parties may be difficult or impossible. The matter will be discussed again during the November 23, 2009, call.

C. Use of X-forms

There was discussion about use of the X-forms. JoAnn Witek (Consultant) noted that some issues with using the XForms are related to the jpg image. She will create a point-by-point description with a solution (that has worked for her) for circulation. On today's (10/5/09) FDA technical Q&A session, it was mentioned that jpg files should be between 1.0 and 2.0 MB, certainly <2.0 MB and preferably <1.0MB. FDA is exploring a validation rule on jpg size limits because extremely large files can impact the efficiency of system.

Pete Carlson (Ecolab) cautioned sub-team members to be diligent about creating and editing sections in the SPL document. The software may have to be reinstalled and corrections may have to be made in programming mode. For problems with using the bold and italics tags for the headings, it was suggested that an earlier version of Foxfire be installed. Howard Shatz (Data Conversion Laboratory) also noted that there may be problems with displaying the name tag for the effective time and the section LOINC code which can be solved by adding the appropriate tag.

D. Draft submission on Posting OTC information to DailyMed/FDA Facts page
Earlier this morning (October 5th), Marcia Howard circulated a draft submission with respect to the issue of posting OTC monograph information to the NLM DailyMed website (or FDA website under development). Because there was not complete consensus about how the listing information for these products should be handled, the letter simply outlining the results of the responses received. **Sub-team members were asked to send any feedback to Marcia by October 13, 2009.** If there are no objections, the letter will be sent to Dr. Randy Levin and Lonnie Smith (both of FDA) on or after October 19, 2009.

MDH/10-12-09

Message received from SPL OTC sub-team member from FDA (identifying information removed):

Requesting UNII for Simethicone

You requested for one UNII to be assigned to simethicone instead of the two substances. It is the FDA Substance Registration System team's position that simethicone can always be listed as a mixture of a given type dimethicone and silicon dioxide.

Due to the amount of recent requests for assignment of a UNII for simethicone by several companies, before we can even consider the assignment a UNII to this term we have some questions.

Note that these are not to be considered as regulatory questions and are only posed as questions due to your request for the assignment of a term to be utilized in the product data elements section of a listing SPL document. You are not obligated in any way to answer these questions and should you opt to reply, your responses will not have any bearing on the approval (if applicable) or listing of your drug.

1. From some of the formulation sheets we have received with requests for an assignment of a UNII for simethicone, it appears that the potency listing is actually based on the amount of dimethicone. Do all the manufactures use a USP grade of simethicone where the amount of silicon dioxide is limited to between 4 and 7%? For example when you list 125 mg/tablet does this mean there will always be between 4 and 9 mg of silicon dioxide and 125 mg of dimethicone or does it mean 125 mg of the mixture dimethicone + silicon dioxide? If there is more than 7% silicon dioxide in a table do you list silicon dioxide as a separate ingredient?
2. What type of dimethicone is typically used? There are a variety of types of Dimethicone each of which differ by molecular weight and would get a separate UNII.
3. Which dimethicones are typically used in the manufacturing of simethicone for pharmaceutical grade material? Is this something that is always controlled? The literature indicates that dimethicones between 20 and 3000 CS are typically used. Unfortunately the USP monograph does the specify the need for the label to indicate the type of dimethicone used.
4. Do manufacturers always use the same type of dimethicone in a given product? The type of dimethicone may influence the performance of the product.